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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/517,264

09/30/2005

Eric Francis Morand

BDW003

1609

20786 7590 06/15/2009  
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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/517,264 | <b>Applicant(s)</b><br>MORAND ET AL. |  |
|                              | <b>Examiner</b><br>SUSANNAH CHUNG    | <b>Art Unit</b><br>1626              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,18-23,26-30 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,18-23,26-30 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |



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### **DETAILED ACTION**

Claims 1, 2, 18-23, 26-30 and 41-43 are pending in the instant application.

Claims 3-17, 24-25, and 31-40 are canceled. Claims 41-43 are new.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS), filed on 3/24/2009 has been considered.

Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Response to Non-Final Office Action***

Acknowledgment is made of applicant's response and amendment of the claims filed on 3/24/2009.

Claims 1, 19, 26, and 28-30 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making prodrugs of the claimed compounds. This rejection is withdrawn in view of the deletion of the term prodrugs.

Claims 1-23 and 26-30 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected because the claims were not enabled for the scope of the compounds and methods claimed.

Applicants arguments have been carefully considered, but are not found persuasive. As stated previously the claims will be give its broadest reasonable interpretation. In view of this rule, the instant claims are drawn to treating, preventing and diagnosing a whole host of disorders and in some claims no disorders at all.



The nonpatent literature submitted on 3/24/2009 has been carefully considered, but are not found persuasive with regard to the instantly claimed disorders wherein the etiology and treatment of are not well known. In general, the nonpatent literature documents submitted focus on expression of macrophage migration inhibitor factor in human cells and the role it may play in the treatment of various disorders.

Unfortunately, the document submitted only speak of the use of the topic in general terms. There were no small molecules used in most of the documents and it appears that the journals discuss the utility in general terms. It does not appear that any of the journals presented use small molecules to treat disorders, rather they all use gene therapy or some type of radiation therapy, which is not being claimed in the instant application. Therefore, the claims are finally rejected as nonenabled.

Claims 1-17, 19-23 and 26-30 were rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for a compound of formula (I), wherein the compound is a specific benzimidazole derivative, wherein a specific alkyl chain is present off the benzimidazole ring, it is not enabled for all definitions claimed without limitation. This rejection is withdrawn in view of the amendment to the claims.

Claims 1-23 and 26-30 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-27 of US Pat App No 12/158,563 (no PGPUb number available). This rejection is maintained in view of Applicants response.

In conclusion, claims 1, 2, 18-23, 26-30 and new claims 41-43 are finally rejected in the instant application.



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/  
Primary Examiner, Art Unit 1626

Susannah Chung